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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,612	10/31/2003	Eric W. Leopold	MICRU:64933	9933

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

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06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,612	LEOPOLD ET AL.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7,9,10 and 13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7,9,10 and 13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 3, 7, 9, 10, 13-17, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (USPN 6,520,986).**

3. Martin discloses an intravascular flow modifier and reinforcement device (stent member 6 only) comprising a generally cylindrical frame consisting of elongate resilient wire (10) configured as a series of helical windings (12). (Note that only member 6 is considered the reinforcement device, not the additional structure of the graft (4), the coupling member (8) or the linking member (20)). Each winding having a series of between 4 and 8 alternating zigzag bends (14) in a rotation of the wire. (Note that the fact that Martin discloses additional structure (i.e. additional windings) is irrelevant). The device has a pre-deployed configuration for placement and a deployed configuration having sharp alternating zigzag bends (14). The zigzag bends are aligned to have a chevron configuration when viewed for a first and second direction transverse to the longitudinal axis (Col 5, lines 50-57 state that the apex portions (16) are aligned so that an apex portion may be displaced into a base portion (18) analogous to the structure of

the instant invention). The zigzag bends have an angle less than about 120 degrees. The helical windings vary in pitch along the longitudinal axis (Fig. 6). The helical windings comprise a series of 4-8 alternating bends that includes either 4 or 6 bends (Fig. 7). The stent is made of superelastic shape memory material that is nitinol (Col 10, lines 45-65). The device is formed by laser cutting (Col 9, line 6).

4. **Claims 1, 3, 7, 9, 10, 13-17 and 23 are rejected under 35 U.S.C. 102(b) as being Das by (USPN 5,554,181).**

5. Das discloses an intravascular flow modifier and reinforcement device (1) comprising a generally cylindrical frame formed of elongate resilient wire (8, Col 6, line 49-50) configured as a series of helical windings (10), each winding having a series of between 4 and 8 alternating zigzag bends (24, 26) in a rotation of the wire (Col 7, lines 30-32). The device has a pre-deployed configuration for placement and a deployed configuration having sharp alternating zigzag bends (24 and 26). The zigzag bends have an angle less than about 120 degrees. The helical windings comprise a series of either 4 or 6 bends (see Fig. 3; Col 7, line 31-32). The wire is made of nitinol, which is shape memory and superelastic (Col 3, line 61-63). Regarding claim 10, the windings of the frame vary in pitch when the device is delivered to a tortuous vessel. Although the intertwining (18) is meant to prevent stretching, the opposite side of the stent will still have the capability to stretch and bend. Therefore it is inherent that when the stent is placed in a vessel with a sharp bend, the pitch or spacing between the windings located

toward the middle of the bend will be greater than the pitch or spacing of the windings toward either end of the stent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ferrera (USPN 6,168,570).**

8. **Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das in view of Ferrera (USPN 6,168,570).**

9. Martin and Das disclose the claimed invention above substantially as claimed except for the wire comprises a stranded cable that is radiopaque.

10. Ferrera discloses a micro-strand cable for use in a stent having a strand of radiopaque material to provide radiopaque markings during therapeutic treatment. Ferrerra teaches that incorporating a radiopaque strand is an advantage because it allows the device to be easily seen in the body and avoids the need to add additional markers to the outside of the device.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate wire that has radiopaque strands or markers into the stent in order to enhance the radiopacity of the stent so that it can be easily tracked during

deployment. It is well known in the art to incorporate radiopacity into stents to easily locate them and to ensure delivery to the correct location. Ferrera offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

12. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Steinke (USPN 6,244,626).**

13. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das in view of Steinke (USPN 6,244,626).**

14. Martin and Das and disclose the claimed invention above substantially as claimed except for a coating.

15. Steinke discloses coating a stent with Parylene in order to provide a lubricious surface, to prevent corrosion and to reduce acute thrombosis.

16. It would have been obvious to one having ordinary skill in the art at the time of the invention coat the stent with a corrosion resistant material such as Parylene since it enhances the properties of the stent by preventing corrosion of the metal while at the same time reducing thrombosis at the treatment site. Steinke offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

17. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Andreacchi (USPN 6,679,980).**

18. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Das in view of Andreacchi (USPN 6,679,980).**

19. Martin and Das disclose the claimed invention above substantially as claimed except for treating the stent with chemical electropolishing.

20. Andreacchi discloses a stent that is electropolished in order to provide a protective corrosion-resistant oxide layer on the stent surface.

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to treat the stent with electropolishing since it enhances the properties of the stent material by protecting the material from corrosion. Andreacchi offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

22. **Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Das.**

23. As to claim 24, Das teaches an intravascular flow modifier and reinforcement device made of elongate resilient wire but is silent as to how the device is made. The claimed phrase "laser cutting" is being treated as a Product by Process limitation, that is the device is formed by laser cutting. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,

698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

24. Thus, even thought Das is silent to the process used to form the device, it appears that the product disclosed by Das would be the same or similar as that claimed; especially since both applicant's product and the prior art product a stent made of elongate resilient wire with helical windings having a pattern sharp alternating zigzag bends.

Response to Arguments

1. Applicant's arguments filed 04/02/07 have been fully considered but they are not persuasive. Applicant's argument that both the Martin reference and the Das reference do not disclose a stent having alternating chevron and reverse chevron configurations is based primarily on the fact that the instant invention has less spacing between adjacent helical windings. However the claim limitations do not distinguish over this structure. The prior art references both disclose stents that align peaks of one winding with peaks of another just as the instant invention does. The prior art references also disclose that the peaks on one winding fit within the base of the adjacent winding (the base being the space below the peak and between the troughs) just as the instant invention does. The peaks are in fact adjacent (near) to the peaks of adjacent helical windings and the valleys are adjacent (near) to valleys of the adjacent helical loops to form a chevron pattern.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh 1/27/09

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
5/29/07